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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,261	05/20/2005	Michael Ploch	166-76	5306

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EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,261	PLOCH ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/7/05;9/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the receipt and entry of amended claims filed on 27 September 2004 with the cancellation of Claims 1-13 and newly entered Claims 14-33.

Claims 14-33 are currently pending.

Claims 14-33 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 27 September 2004 and 7 April 2005 was filed after the mailing date of the Abstract and claims on 27 September 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Each reference with a line through it was not considered because no English translation was provided. In one case, only the abstract was considered because it was the only part of the reference that was translated into English.

Specification

The abstract of the disclosure is objected to for the following reasons: The abstract and the first paragraph on page 1 of the specification recites, "The invention relates to the novel use of plants and plant extracts for treating schizophrenia". It is suggested that the term "novel" be deleted from the language of the abstract. Once the determination of the novelty of a claimed invention has been established and the

disclosure of the invention made public and/or patented, the claimed invention is no longer novel, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of "novel" into the language of the abstract is not appropriate. Appropriate correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 14-33 are objected to because of the following informalities: the Latin names, "Hypericum perforatum", "Ginko biloba", "Crocus Sativus" and "Panax ginseng" (Claims 14 and 24) should be italicized. Also, the appropriate spelling of the Latin name, "Ginko biloba", is *Ginkgo biloba* (Claims 14 and 24), the appropriate spelling of "gingko" is ginkgo (Claims 14, 19 and 25) and the appropriate spelling of "St. John's wart" is St. John's Wort (Claims 14, 18, 23, 25 and 29-33). Appropriate correction is required.

Claims 18, 19-21 and 29-33 are objected to because of the following informalities: Claim 18 reads, "Use according to claim 14, wherein the St. Johns' wart extract used has the following amounts of components" should read, "Use according to claim 14, wherein the St. Johns' wart extract ~~used has the following amounts of~~ comprises the following components". Claims 19-21 and 29-33 require the same type of correction. Appropriate correction is required.

Claim 22 is objected to because of the following informalities: the phrase "wherein the use occurs in the form of liquid, semi-solid and solid forms of administration, in particular solutions, suspensions, tablets, film-coated tablets, dragees,

capsules, effervescent tablets, effercesent granulate, chew tablets and suppositories" should be changed to read, "wherein ~~the use occurs"~~ the medicament may be administered in the form of a liquid, a semi-solid ~~and~~ or a solid ~~forms of administration~~, ~~in particular~~ such as, a solution~~s~~, a suspension~~s~~, a tablet~~s~~, a film-coated tablet~~s~~, a dragee~~s~~, a capsule~~s~~, an effervescent tablet~~s~~, an effercesent granulate, a chew tablet~~s~~ ~~and~~ or ~~suppositories~~ a suppository". The word "effervescent" is misspelled in line 4. Appropriate correction is required.

Claims 23 and 24 are objected to because of the following informalities: Claim 23 currently reads, "wherein the case of St. John's wart extract, the daily dose of the extracts is 300 to 2700 mg in up to 3 separate doses per day, preferably 740-1500 mg in 1-2 separate doses per day", however, Claim 23 should be corrected to read, "wherein ~~the case of~~ St. John's wart extract~~, the daily dose of the extracts is~~ may be administered up to 3 times per day, wherein each dose administered is in an amount of **(or contains)** 300 to 2700 mg **(St. John's wart)**, ~~in up to 3 separate doses per day~~, preferably in an amount of 740-1500 mg administered in 1-2 separate doses per day". Claim 24 also requires the same type of correction. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-24 and 26-33 provide for the use of Hypericum perforatum (St. John's wart) and/or Ginko biloba (gingko) and/or Crocus Sativus (saffron) and/or Panax ginseng (ginseng) for the production of a medicament for the treatment of schizophrenia, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14-24 and 26-33 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 14 are rendered uncertain by the phrase "Use of Hypericum perforatum (St. John's wart) and/or Ginko biloba (gingko) and/or Crocus Sativus (saffron) and/or Panax ginseng (ginseng) for the production of a medicament for the treatment of schizophrenia" is ambiguous because it is unclear as to whether Applicant is claiming a method of treating schizophrenia or a method of making a medicine to treat schizophrenia. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 15 are rendered uncertain by the phrase "wherein the plant, plant parts, dried plant or plant parts, extracts, extract fractions, pure substances and their derivatives and the salts of the plants are used" because it is unclear as to whether Applicant is intending to use all of these components all at once in the medicine or whether each of these parts may be used individually or together. Also the term "pure substances and their derivatives", in line 3, is a relative term which renders the claim indefinite. The term "pure substances" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 15 recites the limitation "the plant" in line 1 and the "the salts" in line 2, both Claim 16 and Claim 27 recite the limitation "the extract" in line 1, Claim 18 and Claims 29-33 all recite the limitation "the St. John's wart extract" in line 1, Claim 19 recites the limitation "the gingko extract" in line 1, Claim 20 recites the limitation "the saffron extract" in line 1 and Claim 21 recites the limitation "the ginseng root extract" in line 1. There is insufficient antecedent basis for these limitations in each claim.

The metes and bounds of Claim 16 are rendered uncertain by the phrase "wherein the extract used is an alcoholic, alcoholic aqueous extract with primary, secondary and tertiary alcohols of series C1 to C5, preferable methanol and ethanol, in the composition of alcohol/water of between 100/0 to 30/70, preferable 80/20 to 50/50" and the metes and bounds of Claim 27 are rendered uncertain by the phrase "Use according to claim 15, wherein the extract used is an alcoholic, alcoholic-aqueous extract with primary, secondary and tertiary alcohols of the series C1 to C5, preferably methanol and ethanol, in the composition of alcohol/water of between 100/0 to 30/70, preferably 80/20 to 50/50" because it is unclear as to what Applicant is claiming. It appears that Applicant is claiming that the plant extracts may either be an alcoholic extract or an aqueous alcohol extract, wherein the alcohol may contain one to five carbon atoms, wherein the alcohol is preferably methanol or ethanol, and wherein the ratio of alcohol to water ranges from 100:0 to 30:70, and more preferably 80/20 to 50/50, however, the claim is written so poorly that it is difficult to tell. Furthermore, it is unclear as to what Applicant is claiming since the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. The

lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 18-21 and 27-33 are rendered uncertain by the phrases "Use according to claim 14, wherein the St. John's wart extract used has the following amounts of components: 0.01 - 2% herpericins, 0.01 - 30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypericins and 1 - 6% hyperforins" in claim 18, the phrase, "Use according to claim 14, wherein the gingko extract has the following amounts and components: 20 - 30% by weight flavone glycosides, together with 2 - 8% of ginkgolides, particularly preferred 23 to 27% flavone glycosides and 5 to 7% by weight ginkgolides" in Claim 19, "Use according to claim 14, wherein the saffron extract comprises the components α-, β-pinene, 1, 8 cineol, crocin, picrocrocin, as well as optionally the degredation product thereof safranal, particularly preferred in the following concentrations: 5 - 10% pinene and cineol, 4 - 10% picrocrocin and/or 2-6% safranal" in Claim 20, "Use according to claim 14, wherein the ginseng root extract comprises the components, interalia, triterpene saponines (ginsenosides/ginsenoids), sesquiterpenes and polyacetylenes, particularly preferred inthefollowing concentrations: 3- 9% ginsenoids" in Claim 21, "Use according to claim 15, wherein the St. John's wart extract used has the following amounts of components: 0.01 - 2% herpericins, 0.01 - 30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypericins and 1 - 6% hyperforins" in Claim 29, "Use according to claim 16, wherein the St. John's wart extract used has the following amounts of components: 0.01 - 2% herpericins, 0.01 - 30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypericins and 1 - 6%

hyperforins" in Claim 30, Use according to claim I7,wherein the St. John's wart extract used has the following amounts of components: 0.01 -2% herpericins, 0.01 -30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypericins and 1 - 6% hyperforins, as Claim 31, "Use according to claim 27, wherein the St. John's wart extract used has the following amounts of components: 0.01 - 2% herpericins, 0.01 - 30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypericins and 1 - 6% hyperforins" in Claim 32 and "Use according to claim 28, wherein the St. John's wart extract used has the following amounts of components: 0.01 - 2% herpericins, 0.01 - 30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypericins and 1 - 6% hyperforins" in Claim 33, because the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 17 and Claim 28 are rendered uncertain by the phrase "Use according to Claim 14, wherein there are produced in a one- and multi-step production process" in Claim 17 and "Use according to Claim 27, wherein there are produced in a one- and multi-step production process" in Claim 28 because it is unclear as to what Applicant is claiming. Applicant could either be saying that the plants are produced in a one-step and a multi-step process or the medicament may be produced inn a one-step and a multi-step process or the treatment of schizophrenia may be produced inn a one-step and a multi-step process (which does not make grammatical sense, if this is the case). The lack of clarity renders the claims indefinite since the

resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 23 and of Claim 24 are rendered uncertain by the phrase "wherein the case of St. John's wart extract, the daily dose of the extracts is 300 to 2700 mg in up to 3 separate doses per day, preferably 750-1500 mg in 1-2 separate doses per day" in Claim 23 and "Use according to claim 14, wherein the case of gingko biloba, Crocis sativus and Panax ginseng, the daily does of the extracts is 50 mg – 1000 mg of extract" because it is unclear as to whether Applicant is claiming that the daily dose of the extract itself is 300 to 2700 mg or if the entire form of administration itself is 300 to 2700 mg. Furthermore these claims are unclear since the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 25 are rendered uncertain by the phrase "Combination preparation containing St. John's wart, gingko, saffron and/or ginseng in addition to, as further components, as psychotherapeutic drug against schizophrenia for the simultaneous, separate or graduated use in the treatment of schizophrenia" is ambiguous because it is unclear as to whether Applicant is claiming that the composition is used in addition to a psychotherapeutic drug to treat schizophrenia or if the psychotherapeutic drug is part of the composition for treating schizophrenia. The

lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 26 are rendered uncertain by the phrase "Use according to claim 14, in add-on therapy in combination with psychotherapeutic drugs for treating schizophrenia, in particular neuroleptics, in particular of the group of classic neuroleptics such as haloperidol, benperidol, chloroprotixene, flupentixol, fluphenazine, perazine, perphenazine, thioridazine, atypical neuroletics, in particular clozapine, olanzapine, seroquel, sertindole, as well as other psychotherapeutic drugs suitable for treating schizophrenia" because it is unclear as to what Applicant is claiming. Applicant could either be claiming additional drugs included in a medicament for treating schizophrenia or that these drugs could be used in addition to a medicament for treating schizophrenia. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-24 and 26-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant claims, "Use of Hypericum perforatum (St. John's wart) and/or Ginko biloba (gingko) and/or Crocus Sativus (saffron) and/or Panax ginseng (ginseng) for the production of a medicament for the treatment of schizophrenia", as Claim 14. It is unclear whether Applicant is claiming a method of using *Hypericum perforatum* (St. John's Wort) and/or *Ginkgo biloba* (ginkgo) and/or *Crocus Sativus* (saffron) and/or *Panax ginseng* (ginseng) or if Applicant is claiming a method of making a medicament for the treatment of schizophrenia comprising *Hypericum perforatum* (St. John's Wort) and/or *Ginkgo biloba* (ginkgo) and/or *Crocus Sativus* (saffron) and/or *Panax ginseng* (ginseng) since no active steps of how to use the claimed product are recited. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Therefore, the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 14-24 and 26-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Song (U, Chinese Patent Abstract, CN 1171264).

Song teaches a medicine in the form of a honey pill or capsule comprising ginseng and sulpiride (which is a medicine for treating schizophrenia) for treating schizophrenia.

Therefore, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
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August 28, 2006

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